EAQA018 / C

Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

Vleria |

Date d'application: 06/07/2011

Surgeon: 174- 1303 hack to Patient Her. (Class)
REPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT
1. Eye ☐ OS
2. Keratrometries K1 43 6 K2 44 K1 Axis 17-3
3. Intra-op full corneal thickness (microns) 53 ☐ □ Ultrasound □ Imaging □ Scheimpflug camera
4. White-to-White (mm)
5 Ametropic correction?
6. Additional comments on the patient's eye
B) MATERIAL
1 Console D Evo2 D Evo3 D Evo3E DOther Serial Number
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™
☐ Evo2 Speed adaptator s/n Speed selection ☐ 1 or ☐ 2 (For M2/M2SU and One Use Plus only)
3 Microkeratome metal head ☐ 150 ☐ 130 ☐ 110 ☐ 90 Serial Number:
4. Handpiece serial number : TU87
r Blade Letter Cingle Use Lott
6. Moria sterile tubing Reference 19138 Batch number : 31 43 6 0 7
7. On approximately how many eyes this specific set had been used before this complication?
8. Ring Disposable Single use DH D-1 D0 -2+1 D+2 D+3 D-1 LC
0.1 Ming
To Stop
C) INTRA-OPERATIVE RESULTS
Characteristics of suction and automated translation:
Was suction time longer or shorter than usual? If yes, suction time? sec
Was the suction good and stable during the pass? □ No
 Was the forward movement smooth and regular?
2. Potential intra-operative events
Pseudo Button-hole Yes No If yes, what was the flap thickness in microns?
Unacceptable thickness ☐ Yes ☐ No
Button-hole ☐ Yes ☐ No
Partial flap ☐ Yes ☐ No
Free cap □ Yes □ No
Decentred Flap □ Yes □ No
Stromal Incursion □ Yes □ No
Epithelium patch ☐ Yes ☐ No The strength is the strength in the pale.
Draw the location of the partial flap or of the pseudo or "see-through" button-hole

EAQA018/C

Approuvé(e) par Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

Date d'application : 06/07/2011

11 Note 21/6/24

Surgeon: Dr. Basharih Patient file#: 1445 + Date 217 57 28				
REPORT OF INTRAOPERATIVE FLAP COMPLICATION				
A) PATIENT				
1 Eve				
2 Keratrometries K1 143.8 K2 144 K1 Axis 26.4				
3. Intra-op full corneal thickness (microns)				
4. White-to-White (mm) 11.4				
- Additional in				
35/4 (1000) (100				
6. Additional comments on the patient's eye				
B) MATERIAL 1. Console				
2. Microkeratome □ ONE □ ONE Use □ CB □ CBSU □ M2 □ M2SU □ ONE Use-Plus □ EPI-k™				
☐ Evo2 Speed adaptator s/n Speed selection ☐1 or ☐2 (For M2/M2SU and One Use Plus on				
3. Microkeratome metal head				
4. Handpiece serial number : 1487				
5 Blade Lot # or Single-Use Lot # : \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\				
6. Moria sterile tubing Reference 19138 Batch number : 3123607				
7. On approximately how many eyes this specific set had been used before this complication?				
Du D4 D0 D+3 D-1 C				
8. King Ubishosable Usingle des				
11. New blade?				
C) INTRA-OPERATIVE RESULTS				
Characteristics of suction and automated translation:				
If yes suction time? sec				
vvas success the total and stable during the page?				
 Was the suction good and stable during the pass? Was the forward movement smooth and regular? 				
VVas tile lollward movement				
2. Potential intra-operative events				
• Pseudo Button-hole Yes No If yes, what was the flap thickness in microns?				
Unacceptable thickness ✓ Yes ☐ No				
Button-hole ☐ Yes ☐ No				
Partial flap				
Free cap □ Yes □ No				
Decentred Flap Yes No				
• Stromal Incursion				
• Epithelium patch				
Draw the location of the partial flap or of the pseudo or "see-through" button-hole				

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Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

Moria

Date d'application : 06/07/2011

14468 **Date** Patient file#: Surgeon: REPORT OF INTRAOPERATIVE FLAP COMPLICATION A) PATIENT OD K2 44-3 K1 Axis 6-3

Diffusion Imaging Scheimpflug camera 1. Eye K1 42.6 2. Keratrometries 3. Intra-op full corneal thickness (microns) 4. White-to-White (mm) ☐ Hyperopic ☐ Astigmatic ☐ Myopic 5 Ametropic correction? 6. Additional comments on the patient's eye B) MATERIAL 2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™ □ Evo2 Speed adaptator s/n _____ Speed selection □ 1 or □ 2 (For M2/M2SU and One Use Plus only) □ 150 □ 130 □ 110 □ 90 Serial Number: __ 3. Microkeratome metal head 4. Handpiece serial number 5. Blade Lot # or Single-Use Lot # 6. Moria sterile tubing Reference 19138 Batch number : 3143602 7. On approximately how many eyes this specific set had been used before this complication? _ 9+1 +2 □H □-1 **0** ☐Single use □Disposable 8. Ring 28 □ 8.5 □ 8.75 □ 9 7 7.5 10 Stop Yes O No (Check "No" for the second eye in bilateral simultaneous LASIK) 11. New blade? C) INTRA-OPERATIVE RESULTS 1. Characteristics of suction and automated translation: If yes, suction time? _____ sec Was suction time longer or shorter than usual? Yes No Was the suction good and stable during the pass? Yes No Was the forward movement smooth and regular? 2. Potential intra-operative events If yes, what was the flap thickness in microns? Pseudo Button-hole ☐ Yes ☐ No Pre-op full corneal thickness Unacceptable thickness ☐ Yes ☐ No Residual stromal bed thickness ☐ Yes ☐ No Button-hole ❖Calculated Flap thickness ☐ Yes ☐ No Partial flap ☐ Yes ☐ No Free cap ☐ Yes ☐ No Decentred Flap ☐ Yes ☐ No Stromal Incursion ☐ Yes ☐ No Epithelium patch

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Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

Moria

Date d'application : 06/07/2011

Patient file#: 144 68 1 Date 14/6/2015

DEDO.	RT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT	RI OF INTRAOPERATIVE TEAL GOING EIGHT CO.
1. Eye	GOD GOS
2. Keratrometries	K1 1.7.6 K2 44.8 K1 Axis 175
Intra-op full corneal thickness	
4. White-to-White (mm)	Myopic Hyperopic Astigmatic
5 Ametropic correction?	
6. Additional comments on the	patient's eye
B) MATERIAL 1. Console □ Evo2 □ Evo3	Evo3E Other Serial Number :
2. Microkeratome ☐ ONE ☐	ONE Use □ CB □ CBSU □ M2 □ M2SU □ ONE Use-Plus □ EPI-k™
□ Evo2 Speed adaptator s	s/n Speed selection □1 or □2 (For M2/M2SU and One Use Plus only
3. Microkeratome metal head	□ 150 □ 130 □ 110 □ 90 Serial Number:
4. Handpiece serial number	1487
5 Blade Lot # or Single-Use Lo	ot# : ([(4 ^_
6.Moria sterile tubing Reference	e 19138 Batch number _: 314360 2
7 On approximately how many	eyes this specific set had been used before this complication?
8. Ring Disposable	□Single use □ H □ -1 □ 0 □ +1 □ +2 □ +3 □ -1 LC
10 Stop	□7 □7.5 □8 □8.5 □8.75 □9 □Other
11. New blade?	☐ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK)
C) INTRA-OPERATIVE RESUL	10
1. Characteristics of suction ar	
	ger or shorter than usual? If yes, suction time? sec
	and stable during the pass?
 Was the forward mov 	ement smooth and regular? ☐ Yes ☐ No
2. Potential intra-operative eve	ents
 Pseudo Button-hole 	☐ Yes ☐ No If yes, what was the flap thickness in microns?
 Unacceptable thickne 	ess • Yes • No • Pre-op full corneal thickness
 Button-hole 	☐ Yes ☐ No
 Partial flap 	☐ Yes ☐ No
 Free cap 	☐ Yes ☐ No
 Decentred Flap 	□ Yes □ No
 Stromal Incursion 	☐ Yes ☐ No
 Epithelium patch 	☐ Yes ☐ No
Draw the location of the p	artial flap or of the pseudo or "see-through" button-hole

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Approuvé(e) par Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

Moria

Date d'application : 06/07/2011

14/6/2015 14361

Surgeon: Basherkh Patient file#: 1436 Date 14/6/2
REPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT
4 Fire
2. Keratrometries K1 <u>((3)</u> K2/ <u>(5, 7)</u> K1 Axis <u>(3, 7)</u>
3. Intra-op full corneal thickness (microns) 527
4. White-to-White (mm) 1. 8
D. I. J. Astigmatic
6. Additional comments on the patient's eye
1. Console Evo2 Evo3 Evo3E Other Serial Number :
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™
☐ Evo2 Speed adaptator s/n Speed selection ☐ 1 or ☐ 2 (For M2/M2SU and One Use Plus only
3. Microkeratome metal head
4. Handpiece serial number : 1487
5 Plade Let # or Single-Use Let #
6. Moria sterile tubing Reference 19138 Batch number : 9143602
7. On approximately how many eyes this specific set had been used before this complication?
8. Ring Disposable Single use H -1 0 +2 +1 +2 +3 -1LC
10 Stop
11. New blade? Yes \(\square\) No (Check "No" for the second eye in bilateral simultaneous LASIK)
C) INTRA-OPERATIVE RESULTS
Characteristics of suction and automated translation:
Was suction time longer or shorter than usual? If yes, suction time? sec
Was the suction good and stable during the pass? ☐ Yes ☐ No
Was the forward movement smooth and regular? □ No
2. Potential intra-operative events
Pseudo Button-hole □ Yes □ No If yes, what was the flap thickness in microns?
Unacceptable thickness ☐ Yes ☐ No
Button-hole □ Yes □ No
Partial flap ☐ Yes ☐ No
Free cap □ Yes □ No The cap □ Yes □ No The cap □ Yes □ No
Decentred Flap ☐ Yes ☐ No Stromal Incursion ☐ Yes ☐ No
and the state of t
 Epithelium patch
DIGHT AND TOUGHOUSE AND PERSONS

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Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

THE STATE OF THE S

Moria

Date d'application : 06/07/2011

Surgeon: Dr. Basker Patient file#: 14)61 4 Date 14/8/
REPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT
1. Eye OD GOS
2. Keratrometries K1 43 K2 44.4 K1 Axis 172.5
3. Intra-op full corneal thickness (microns) 533
4. White-to-White (mm) 1/1 8
5 Ametropic correction?
6. Additional comments on the patient's eye
B) MATERIAL 1. Console
2 Microkeratome □ ONE □ ONE Use □ CB □ CBSU □ M2 □ M2SU □ ONE Use-Plus □ EPI-K····
☐ Evo2 Speed adaptator s/n Speed selection ☐1 or ☐ 2 (For M2/M2SU and One Use Plus or
3. Microkeratome metal head
4. Handpiece serial number : 1487
7 Die Leit Her Circle Hee Let # 117/1/1/12
6. Moria sterile tubing Reference 19138 Batch number : 31 43 60 7
7. On approximately how many eyes this specific set had been used before this complication?
8. Ring UDisposable USingle use UT U U U U U U U U U U U U U U U U U U
10 Stop
1 10 10 10 10 10 10 10 10 10 10 10 10 10
C) INTRA-OPERATIVE RESULTS
Characteristics of suction and automated translation:
Was suction time longer or shorter than usual? If yes, suction time? sec
 Was the suction good and stable during the pass?
 Was the forward movement smooth and regular?
a. Dut with links apporative events
2. Potential intra-operative events ■ Pseudo Button-hole □ Yes □ No If yes, what was the flap thickness in microns?
Pseudo Button-hole ☐ Yes ☐ No If yes, what was the hap thickness if finicions? Unacceptable thickness ☐ Yes ☐ No
Button-hole □ Yes □ No
Partial flap ☐ Yes ☐ No
Free cap □ Yes □ No
Decentred Flap □ Yes □ No
Stromal Incursion □ Yes □ No
Epithelium patch □ Yes □ No The street line is a street line in the street line is a street line in the street line is a street line in the street line in the street line is a street line in the street line in the street line is a street line in the street line in the street line is a street line in the s
Draw the location of the partial flap or of the pseudo or "see-through" button-hole

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Approuvé(e) par Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

Date d'application : 06/07/2011

Moria

Surgeon: Dr. Basheikh Patient file#: 14628 Date 21/6/201
REPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT
1 Eve □ OS
2. Keratrometries K1 4 - 5 K2 4 - 1 K1 Axis H5
3. Intra-op full corneal thickness (microns) 548 □ Ultrasound □ Imaging □Scheimpflug camera
4. White-to-White (mm)
5 Ametropic correction? Myopic Hyperopic Astigmatic
6. Additional comments on the patient's eye
1. Console Evo2 Evo3 Evo3E Other Serial Number : 8 (/ 3
2 Microkeratome □ ONE □ ONE Use □ CB □ CBSU □ M2 □ M2SU □ ONE Use-Plus □ EPI-k™
□ Evo2 Speed adaptator s/n Speed selection □ 1 or □ 2 (For M2/M2SU and One Use Plus only)
3. Microkeratome metal head
4. Handpiece serial number : 1487
m mi i i i i i i i i i i i i i i i i i
6. Moria sterile tubing Reference 19138 Batch number : 3143602
7. On approximately how many eyes this specific set had been used before this complication?
Dollarda 1992 1991 1991 1991 1992 1993 1991 1992
6. King abioposasis
10 Stop 11. New blade? 12. No (Check "No" for the second eye in bilateral simultaneous LASIK)
C) INTRA-OPERATIVE RESULTS
Characteristics of suction and automated translation:
Was suction time longer or shorter than usual? If yes, suction time? sec
Was the suction good and stable during the pass? □ Yes □ No
 Was the forward movement smooth and regular? ☐ Yes ☐ No
2. Potential intra-operative events
Pseudo Button-hole Yes No If yes, what was the flap thickness in microns?
Linacceptable thickness □ Yes □ No
Button-hole □ Yes □ No
Partial flap □ Yes □ No
• Free cap
Decentred Flap Yes No
• Stromal Incursion
 Epithelium patch
Draw the location of the parties may at the parties

Moria

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Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

Date d'application : 06/07/2011

Date Patient file#: Surgeon: REPORT OF INTRAOPERATIVE FLAP COMPLICATION A) PATIENT OD 1. Eye K2423 K1 Axis 5 K1 112.2 2. Keratrometries ☐ Ultrasound ☐ Imaging ☐ Scheimpflug camera 3. Intra-op full corneal thickness (microns) 4. White-to-White (mm) 12.00 ☐ Hyperopic ☐ Astigmatic Myopic 5 Ametropic correction? 6. Additional comments on the patient's eye _ B) MATERIAL 1. Console □ Evo2 □ Evo3 Ū Evo3E □ Other Serial Number 2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™ □ Evo2 Speed adaptator s/n _____ Speed selection □ 1 or □ 2 (For M2/M2SU and One Use Plus only) □ 150 □ 130 □ 110 □ 90 Serial Number: _____ 3. Microkeratome metal head 4. Handpiece serial number 5. Blade Lot # or Single-Use Lot # 6.Moria sterile tubing Reference 19138 Batch number _: 314 3602 7. On approximately how many eyes this specific set had been used before this complication? _ □ +3 □ -1 LC OH O-1 90 □ +1 □ +2 ☐Single use □Disposable 8. Ring 28 □ 8.5 □ 8.75 □ 9 **□**Other **7.5 1** 7 10 Stop ☐ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK) 11. New blade? C) INTRA-OPERATIVE RESULTS 1. Characteristics of suction and automated translation: If yes, suction time? _____ sec Was suction time longer or shorter than usual? ☐ Yes ☐ No Was the suction good and stable during the pass? Yes No Was the forward movement smooth and regular? 2. Potential intra-operative events If yes, what was the flap thickness in microns? ☐ Yes ☐ No Pseudo Button-hole Pre-op full corneal thickness Unacceptable thickness - Yes O No Residual stromal bed thickness ☐ Yes ☐ No Button-hole ❖Calculated Flap thickness ☐ Yes ☐ No Partial flap ☐ Yes ☐ No Free cap ☐ Yes ☐ No Decentred Flap ☐ Yes ☐ No Stromal Incursion ☐ Yes ☐ No Epithelium patch

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Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

4

Moria

Date d'application: 06/07/2011

Surgeon: Ah	tinto puise	//) Patient	Tile#:		Date	
	REPORT OF	INTRAOPER	ATIVE FLAF	COMPLICAT	TION	
A) PATIENT						
1. Eye	100	Z OD	NA-	1 OS	-	
2. Keratrometries		K1 42.0	K2 43.	2 K1 Axis2	<u>3</u> -1	
3. Intra-op full corr	neal thickness (micr	ons) 507	☑ Ultrasou	und 🗆 Imaging	□Scheimpflug	camera
4. White-to-White	(mm)	PENTO	can Hr.			
5 Ametropic correc		Myopic	☐ Hypero	pic 🚨 Astigm	atic	
	ments on the patient	's eye				-
2000 - C00000000000000000000000000000000				6	113	
1 Console DEV	vo2 □ Evo3 ☑ E	vo3E □Other	Serial Numb	oer : <u>8</u>		. 711
2. Microkeratome	ONE ONE	Use 🗆 CB 🗆	CBSU IM2	☐ M2SU ☐ O	NE Use-Plus	EPI-k' [™]
☐ Evo2 Speed	adaptator s/n	Speed se	election 41 or	r □ 2 (For M2/	M2SU and One U	se Plus only)
3. Microkeratome		150 🗆 130 🗀	110 🗆 90 🛭	Serial Number: _		
25 / W. C.		: 1148	7 SBK	7		
5 Blade Lot # or 5	Single-Use Lot#	KINGLE !	WE LOT:	1144112		
Moria sterile tub	ing Reference 1913	38 Batch number	er :	000		
7. On approximate	ely how many eyes	this specific set	had been used	d before this cor	mplication?	_
		gle use	H .2 -1 (0 0+1	□ +2 □ +3	□ -1 LC
10 Stop	□ 7	□ 7.5 □	8 28.5	□ 8.75 □ 9	□Other	_
11. New blade?	DY	s 🗆 No (Check	("No" for the s	econd eye in bil	ateral simultaneou	ıs LASIK)
C) INTRA-OPERAT						
8						
	of suction and auto			.2		
	ction time longer or			If yes, s ✓ Yes	uction time?	_ sec
	suction good and s			Yes		
 Was the 	forward movement	smooth and reg	jular?	163	4 140	
2. Potential intra-	operative events					
		Yes □ No			ness in microns?	
 Unacce 	ptable thickness 🕰	Yes □ No			rneal thickness	507
 Button-h 	11.5(2.5)	Yes □ No			mal bed thickness	43+
 Partial f 		Yes □ No			ap mickness	40
Free ca	End	Yes □ No				
	ou i iup	Yes ☐ No Yes ☐ No				a
	i ilioure.e	Yes 🗆 No		_	i.	27

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Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

4

Moria

Date d'application : 06/07/2011

Surgeon: GHMTD HULLEN Patient file#: 14568 Date 13/06/20	2:5
REPORT OF INTRAOPERATIVE FLAP COMPLICATION	
A) PATIENT	
1 500 Ø OS	
2 Karatrometries K1 41.8 K2 43.4 K1 Axis 1620	
3. Intra-op full corneal thickness (microns) √∑ √ □ □ Ultrasound □ Imaging □ Scheimpflug camera	
4. White-to-White (mm) 12-1 min DENT CLEAR ITM	
—	
6. Additional comments on the patient's eye	
B) MATERIAL 1. Console	
2 Microkeratome ONE ONE Use CB CBSU M2 M2SU CAONE Use-Plus CEPI-k	18 1
□ Evo2 Speed adaptator s/n Speed selection □ 2 (For M2/M2SU and One Use Plus of	only
3. Microkeratome metal head	
4 Handriggs carial number 11487 SBK	
5. Blade Lot # or Single-Use Lot # : SING LE USE LOT. 11 44 112	
6.Moria sterile tubing Reference 19138 Batch number : 3143607	
7. On approximately how many eyes this specific set had been used before this complication?	
$\square \square $	С
6. King adisposable 25 D. 75 D. 9 D. 75 D. 9 DOther	
10 Stop	()
C) INTRA-OPERATIVE RESULTS	
1. Characteristics of suction and automated translation:	
Was suction time longer or shorter than usual? If yes, suction time? sec	
 Was the suction good and stable during the pass? 	
 Was the forward movement smooth and regular? Yes □ No	
2. Potential intra-operative events	
Pseudo Button-hole ☐ Yes ☐ No ☐ If yes, what was the flap thickness in microns?	
 Unacceptable thickness ☐ Yes ☐ No Pre-op full corneal thickness 	0
 Button-hole Yes ☐ No Residual stromal bed thickness ☐ (4) 	8
 Partial flap Yes □ No Calculated Flap thickness 	61
Free cap □ Yes □ No	
Decentred Flap □ Yes □ No	
Stromal Incursion □ Yes □ No The Stromatic Str	
 Epithelium patch Yes No Draw the location of the partial flap or of the pseudo or "see-through" button-hole 	
Draw the location of the partial flap of of the pseudo of see-through button hole	

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Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

4

Date d'application : 06/07/2011

Moria

Husselm Surgeon: REPORT OF INTRAOPERATIVE FLAP COMPLICATION A) PATIENT WOD □ os 1. Eye K2 15 K1 Axis 3. 2 K1 44.2 2. Keratrometries ☐ Ultrasound ☐ Imaging ☐ Scheimpflug camera 3. Intra-op full corneal thickness (microns) <a>4 <a>5 4. White-to-White (mm) 12-2 Pentacan HR 5 Ametropic correction? Myopic ☐ Hyperopic ☐ Astigmatic 6. Additional comments on the patient's eye __ B) MATERIAL 1. Console ☐ Evo2 ☐ Evo3 ☐ Evo3E ☐ Other Serial Number 2. Microkeratome □ ONE □ ONE Use □ CB □ CBSU □ M2 □ M2SU □ ONE Use-Plus □ EPI-k™ □ Evo2 Speed adaptator s/n ______ Speed selection □1 or □ 2 (For M2/M2SU and One Use Plus only) □ 150 □ 130 □ 110 □ 90 3. Microkeratome metal head Serial Number: _____ 4. Handpiece serial number : Singlupe LOT 2 1144 112 5. Blade Lot # or Single-Use Lot # 6. Moria sterile tubing Reference 19138 Batch number : 3143 602 7. On approximately how many eyes this specific set had been used before this complication? □ H □ -1 40 □ +1 □ +2 8. Ring □ Disposable ☐Single use □8 □8.5 □8.75 □9 **7.5** □Other **D**7 10 Stop ✓ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK) 11. New blade? C) INTRA-OPERATIVE RESULTS 1. Characteristics of suction and automated translation: Was suction time longer or shorter than usual? If yes, suction time? sec ☑ Yes ☐ No Was the suction good and stable during the pass? Was the forward movement smooth and regular? Yes ☐ No 2. Potential intra-operative events Pseudo Button-hole ☐ Yes ☐ No If yes, what was the flap thickness in microns? Pre-op full corneal thickness Unacceptable thickness > Yes No ☐ Yes ☐ No ❖Residual stromal bed thickness 51/1 Button-hole

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

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☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No
☐ Yes ☐ No

Partial flap

Decentred Flap Stromal Incursion

Epithelium patch

Free cap

2

❖Calculated Flap thickness

EAQA018/C

Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

4

Date d'application : 06/07/2011

Moria

Surgeon: Almed Hussein Patient file#: 1456 Date 15/6/2015				
REPORT OF INTRAOPERATIVE FLAP COMPLICATION				
A) PATIENT				
1. Eye OD S				
2. Keratrometries K1 <u>43.7</u> K2 <u>45.7</u> K1 Axis <u>171.3</u>				
3. Intra-op full corneal thickness (microns)				
4. White-to-White (mm) 12.3				
5 Ametropic correction?				
6. Additional comments on the patient's eye				
B) MATERIAL 1. Console □ Evo2 □ Evo3 □ Evo3E □Other Serial Number : 8/13				
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™				
☐ Evo2 Speed adaptator s/n Speed selection ☐ or ☐ 2 (For M2/M2SU and One Use Plus only)				
3. Microkeratome metal head				
4. Handpiece serial number : 1487				
5. Blade Lot # or Single-Use Lot # : Single use 1144112 6. Moria sterile tubing Reference 19138 Batch number : 3113602				
7. On approximately how many eyes this specific set had been used before this complication?				
8. Ring				
10 Stop				
11. New blade? Yes TNo (Check "No" for the second eye in bilateral simultaneous LASIK)				
C) INTRA-OPERATIVE RESULTS				
O) INTRA-OF ENAMYE RESOURS				
Characteristics of suction and automated translation:				
 Was suction time longer or shorter than usual? ✓ ✓ If yes, suction time? sec 				
 Was the suction good and stable during the pass? 				
 Was the forward movement smooth and regular? 				
2. Potential intra-operative events				
Pseudo Button-hole ☐ Yes ☐ No ☐ If yes, what was the flap thickness in microns?				
 Unacceptable thickness ☐ Yes ☐ No ❖Pre-op full corneal thickness 				
 Button-hole ☐ Yes ☐ No ❖Residual stromal bed thickness 				
Partial flap □ Yes □ No				
Free cap □ Yes □ No				
Decentred Flap □ Yes □ No				
Stromal Incursion □ Yes □ No				
Epithelium patch □ Yes □ No				
Draw the location of the partial flap or of the pseudo or "see-through" button-hole				

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EAQA018 / C

Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

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Meria

Date d'application : 06/07/2011

Surgeon: SHMED HUSSEIN Patient file#: 1450 Date 10 1061
REPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT
GOD □ OS
2. Keratrometries K1 42. 9 K2 43. 4 K1 Axis 26. 9
3. Intra-op full corneal thickness (microns)
4. White-to-White (mm) 11. 5 Pentacan the
O / Milotropio de la companya de la
6. Additional comments on the patient's eye
B) MATERIAL 1. Console
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU → ☐ ONE Use-Plus ☐ EPI-k™
□ Evo2 Speed adaptator s/n Speed selection □ 1 or □ 2 (For M2/M2SU and One Use Plus or
3. Microkeratome metal head ☐ 150 ☐ 130 ☐ 110 ☐ 90 Serial Number:
4. Handpiece serial number : 1187 CBK
5. Blade Lot # or Single-Use Lot # : SinGt U(E 101 : 1144 11)
6.Moria sterile tubing Reference 19138 Batch number : 3143 602
7. On approximately how many eyes this specific set had been used before this complication?
8. Ring Disposable Single use DH D-1 D0 -D+1 D+2 D+3 D-1 LC
10 Stop
11. New blade? ☐ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK)
C) INTRA-OPERATIVE RESULTS
 Characteristics of suction and automated translation:
Was suction time longer or shorter than usual? If yes, suction time? sec
Was the suction good and stable during the pass? □ Yes □ No □ No
 Was the forward movement smooth and regular?
2. Potential intra-operative events
 Pseudo Button-hole Yes No If yes, what was the flap thickness in microns?
Unacceptable thickness ☐ Yes ☐ No
Button-hole ☐ Yes ☐ No
Partial flap □ Yes □ No
• Free cap
Decentred Flap □ Yes □ No This □ Yes □ No
Stromal Incursion □ Yes □ No Fpithelium patch □ Yes □ No
• Epithelium patch

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Date d'application : 06/07/2011

Surgeon: CHINEN HISSEM

Meria

Patient file#:

14500

Date 10/06/2013

REPORT OF INTRAOPERATIVE FLAP COMPLICATION A) PATIENT Z os OD OD 1. Eye K2 43.3 K1 Axis 2 = 6 K143.0 2. Keratrometries 3. Intra-op full corneal thickness (microns) 410 ☐ Ultrasound ☐ Imaging ☐ Scheimpflug camera 4. White-to-White (mm) 11-4 mm pentacom ☐ Hyperopic ☐ Astigmatic Myopic 5 Ametropic correction? 6. Additional comments on the patient's eye _ **B) MATERIAL** 8 113 1. Console □ Evo2 □ Evo3 ☑ Evo3E □Other Serial Number 2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™ □ Evo2 Speed adaptator s/n _____ Speed selection □1 or □ 2 (For M2/M2SU and One Use Plus only) □ 150 □ 130 □ 110 □ 90 Serial Number: _ 3. Microkeratome metal head . JIURT SAIC 4. Handpiece serial number : SINCLE WE LOT : 1144 112 5. Blade Lot # or Single-Use Lot # 6.Moria sterile tubing Reference 19138 Batch number <u>: 314 ろら</u>ひ ン 7. On approximately how many eyes this specific set had been used before this complication? 4+1 □ +2 +3 00 ΠН **-1** ☐Single use 8. Ring □Disposable 2 8 □ 8.5 □Other □ 8.75 □ 9 **7.5** 10 Stop ☐ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK) 11. New blade? C) INTRA-OPERATIVE RESULTS 1. Characteristics of suction and automated translation: If yes, suction time? _____ sec Was suction time longer or shorter than usual? ☐ Yes ☐ No Was the suction good and stable during the pass? Yes No Was the forward movement smooth and regular? 2. Potential intra-operative events If yes, what was the flap thickness in microns? Pseudo Button-hole ☐ Yes ☐ No ❖Pre-op full corneal thickness Unacceptable thickness ✓ Yes ☐ No Residual stromal bed thickness ☐ Yes ☐ No Button-hole ❖Calculated Flap thickness ☐ Yes ☐ No Partial flap ☐ Yes ☐ No Free cap ☐ Yes ☐ No Decentred Flap ☐ Yes ☐ No Stromal Incursion ☐ Yes ☐ No Epithelium patch Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EA	QA018 / C	Approuvé(e) par : Jean Paul MERCEREAU
Moria	Date d'application : 06/07/2011		5 1 5 10 10 10 10 10 10 10 10 10 10 10 10 10	Directeur Assurance Qualité e Affaires réglementaires le 06/07/2011 16:03:48

Surgeon: CITMED thisself Patient file#: 14508 1 Date 10/06/20				
REPORT OF INTRAOPERATIVE FLAP COMPLICATION				
A) PATIENT				
1. Eye ☐ OS				
2. Keratrometries K1 47 - 1 K2 42 - 6 K1 Axis S - 1				
3. Intra-op full corneal thickness (microns) 533				
4. White-to-White (mm) 12-3 PENTAGE + HR				
5 Ametropic correction? ☐ Myopiç ☐ Hyperopic ☐ Astigmatic				
6. Additional comments on the patient's eye				
B) MATERIAL				
1. Console ☐ Evo2 ☐ Evo3 ☐ Evo3E ☐ Other Serial Number : 8 113				
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™				
☐ Evo2 Speed adaptator s/n Speed selection—☐ or ☐ 2 (For M2/M2SU and One Use Plus only)				
3. Microkeratome metal head ☐ 150 ☐ 130 ☐ 110 ☐ 90 Serial Number:				
4. Handpiece serial number : J1487 SBK				
5. Blade Lot # or Single-Use Lot # : SINGLE LUE LOT : ILY LIZ				
6.Moria sterile tubing Reference 19138 Batch number : 3143602				
7. On approximately how many eyes this specific set had been used before this complication?				
8. Ring Disposable Dis				
10 Stop				
11. New blade?				
C) INTRA-OPERATIVE RESULTS				
Characteristics of suction and automated translation:				
Was suction time longer or shorter than usual? If yes, suction time? sec				
Was the suction good and stable during the pass? □ Yes □ No				
Was the forward movement smooth and regular? □ No				
2. Potential intra-operative events				
Pseudo Button-hole ☐ Yes ☐ No ☐ If yes, what was the flap thickness in microns?				
 Unacceptable thickness ✓ Yes ✓ No Pre-op full corneal thickness ✓ 33 				
Button-hole ☐ Yes ☐ No				
Partial flap □ Yes □ No				
Free cap □ Yes □ No				
Decentred Flap ☐ Yes ☐ No				
Stromal Incursion □ Yes □ No				
Epithelium patch ☐ Yes ☐ No				
Draw the location of the partial flap or of the pseudo or "see-through" button-hole				

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Date d'application : 06/07/2011

Вате и аррисатоп : 00/07/2011

attento

Meria

Surgeon:

Hassein Patient file#: 14508 Date 10/04/2015

DEDORT OF INTRAODERATIVE ELABORATIVE
A) PATIENT
1. Eye ☐ OD ☐ OS
2. Keratrometries K1 42.4 K2 42.6 K1 Axis 157.4
3. Intra-op full corneal thickness (microns) <u>₹₹</u> □Ultrasound □ Imaging □Scheimpflug camera
4. White-to-White (mm) 12.1 PENTOICAM +M
5 Ametropic correction? ☐ Myopiç ☐ Hyperopic ☐ Astigmatic
6. Additional comments on the patient's eye
B) MATERIAL 1. Console □ Evo2 □ Evo3 □ Evo3E □Other Serial Number : 8 (13
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™
□ Evo2 Speed adaptator s/n Speed selection □ 1 or □ 2 (For M2/M2SU and One Use Plus only
3. Microkeratome metal head
4. Handpiece serial number : J1487 SOK
5. Blade Lot # or Single-Use Lot # : SINGLE USE LOT : ILYY IT
6. Moria sterile tubing Reference 19138 Batch number : 3 143 602
7. On approximately how many eyes this specific set had been used before this complication?
8. Ring Disposable Dsingle use H 2-1 0 0 +1 +2 +3 0-1 LC
10 Stop
11. New blade?
C) INTRA-OPERATIVE RESULTS
Characteristics of suction and automated translation:
Was suction time longer or shorter than usual? If yes, suction time? sec
Was the suction good and stable during the pass? ✓ Yes □ No ✓ Yes □ No
Was the forward movement smooth and regular? ☐ Yes ☐ No
2. Potential intra-operative events
 Pseudo Button-hole ☐ Yes ☐ No If yes, what was the flap thickness in microns?
 Unacceptable thickness ☑ Yes ☐ No ❖Pre-op full corneal thickness
 Button-hole ☐ Yes ☐ No ☆Residual stromal bed thickness
Partial flap ☐ Yes ☐ No
• Free cap
Decentred Flap ☐ Yes ☐ No
Stromal Incursion
• Epithelium patch
Draw the location of the partial flap or of the pseudo or "see-through" button-hole

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Moria

Date d'application : 06/07/2011

Surgeon: Ahmad	Hussun Patient file#: 14577 Date
	EPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT 1. Eye 2. Keratrometries 3. Intra-op full corneal third 4. White-to-White (mm) 5 Ametropic correction?	K1 42 V K2 43 2K1 Axis 162 Scheimpflug camera Skness (microns) 560 Sultrasound Imaging Ischeimpflug camera 1-6 mm Putacam Myopic I Hyperopic Astigmatic In the patient's eye
2. Microkeratome □ ON □ Evo2 Speed adapt 3. Microkeratome metal I 4. Handpiece serial num 5. Blade Lot # or Single- 6.Moria sterile tubing Re 7. On approximately how 8. Ring □ Disposable 10 Stop	Der : 11487 SBC Use Lot # : CINAL USE LOT 144112 ference 19138 Batch number : 314 3602 many eyes this specific set had been used before this complication? Single use
11. New blade? C) INTRA-OPERATIVE R	✓ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK) ESULTS
Was suction tirWas the suctioWas the forward	tion and automated translation: ne longer or shorter than usual? n good and stable during the pass? If yes, suction time? sec If yes, suction time? sec
 Button-hole Partial flap Free cap Decentred Fla Stromal Incurs Foithelium pal 	hole

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Moria

Date d'application : 06/07/2011

Surgeon: CHINED HUGEIN Patient file#: 14516 Date 10/0

REPORT OF INTRAOPERATIVE FLAP COMPLICATION A) PATIENT OD D 1. Eye □ os K1 42.0 2. Keratrometries K2 42. 4 K1 Axis 23.0 3. Intra-op full corneal thickness (microns) 573 ☑Ultrasound ☐ Imaging ☐Scheimpflug camera 11.9 HM PENTACSM 4. White-to-White (mm) 5 Ametropic correction? Myopic Myopic ☐ Hyperopic ☐ Astigmatic 6. Additional comments on the patient's eye _ B) MATERIAL : 813 1. Console ☐ Evo2 ☐ Evo3 ☐ Evo3E ☐ Other Serial Number 2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™ □ Evo2 Speed adaptator s/n _____ Speed selection □1 or □2 (For M2/M2SU and One Use Plus only) □ 150 □ 130 □ 110 □ 90 3. Microkeratome metal head Serial Number: : J1427 SBK 4. Handpiece serial number : SIAGLE UST LOT: 1144112 5. Blade Lot # or Single-Use Lot # 6.Moria sterile tubing Reference 19138 Batch number : 314 3 602 7. On approximately how many eyes this specific set had been used before this complication? ___ 8. Ring □Disposable ☐Single use □H □-1 □0 □+1 □ +2 □ +3 □ -1 LC 28 □ 8.5 □ 8.75 □ 9 10 Stop **0** 7 **7.5** Yes I No (Check "No" for the second eye in bilateral simultaneous LASIK) 11. New blade? C) INTRA-OPERATIVE RESULTS 1. Characteristics of suction and automated translation: Was suction time longer or shorter than usual? If yes, suction time? sec Was the suction good and stable during the pass? Yes No Was the forward movement smooth and regular? → Yes □ No 2. Potential intra-operative events Pseudo Button-hole ☐ Yes ☐ No If yes, what was the flap thickness in microns? Unacceptable thickness Yes No ❖Pre-op full corneal thickness Button-hole ☐ Yes ☐ No Residual stromal bed thickness Partial flap ☐ Yes ☐ No Calculated Flap thickness Free cap ☐ Yes ☐ No Decentred Flap ☐ Yes ☐ No Stromal Incursion ☐ Yes ☐ No Epithelium patch ☐ Yes ☐ No

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Date d'application : 06/07/2011

Moria

Surgeon: Off MED #USSEID Patient file#: Date
REPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT
1. Eye □ OD □ OS
2. Keratrometries K1 K2 K1 Axis
3. Intra-op full corneal thickness (microns) ☐ ☐ Ultrasound ☐ Imaging ☐ Scheimpflug camera
4. White-to-White (mm) PENTOCOM #R
5 Ametropic correction?
6. Additional comments on the patient's eye
B) MATERIAL 1. Console □ Evo2 □ Evo3 □ Evo3E □Other Serial Number : _ 8 11 3
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™
☐ Evo2 Speed adaptator s/n Speed selection ☐1 or ☐ 2 (For M2/M2SU and One Use Plus only
3. Microkeratome metal head ☐ 150 ☐ 130 ☐ 110 ☐ 90 Serial Number:
4. Handpiece serial number : Jys 7 SBK
5. Blade Lot # or Single-Use Lot # : SINGLE USE LOT: 1144112
6.Moria sterile tubing Reference 19138 Batch number 3 14360 2
7. On approximately how many eyes this specific set had been used before this complication?
8. Ring
10 Stop
11. New blade?
C) INTRA-OPERATIVE RESULTS
Characteristics of suction and automated translation:
Was suction time longer or shorter than usual? If yes, suction time? sec
Was the suction good and stable during the pass? Yes □ No
Was the forward movement smooth and regular? □ Yes □ No
2. Potential intra-operative events
 Pseudo Button-hole ☐ Yes ☐ No If yes, what was the flap thickness in microns?
 Unacceptable thickness
Button-hole □ Yes □ No
Partial flap ☐ Yes ☐ No
• Free cap
Decentred Flap ☐ Yes ☐ No Stromal Incursion ☐ Yes ☐ No
Stromal Incursion □ Yes □ No Epithelium patch □ Yes □ No
Draw the location of the partial flap or of the pseudo or "see-through" button-hole
Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Moria

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Approuvé(e) par Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

t'application : 06/07/2011

Surgeon: Ahmod Hussein Patient file#: 1460h pate 16 June 2013

REPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT
1. Eye OD OS
2. Keratrometries K1 4.0 K2 47.0 K1 Axis 776.6
3. Intra-op full corneal thickness (microns) <u>∫</u> (□ □ Ultrasound □ Imaging □ Scheimpflug camera
4. White-to-White (mm) 12-0mm Pentacam
5 Ametropic correction?
6. Additional comments on the patient's eye
Secretary and and the secretary and the secretar
B) MATERIAL 1. Console
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™
□ Evo2 Speed adaptator s/n Speed selection □ 1 or □ 2 (For M2/M2SU and One Use Plus only
AND DESCRIPTION OF THE PROPERTY AND ADDRESS OF THE PROPERTY OF
o. Milotokalatina mata
4. Handpiece serial number : TUST 15K
5. Blade Lot # or Single-Use Lot # : SIMPLE USE UNT 144117
6.Moria sterile tubing Reference 19138 Batch number : <u>カリッカル</u> のレ
On approximately how many eyes this specific set had been used before this complication?
8. Ring Disposable Dis
10 Stop □ 7 □ 7.5 □ 8 □ 8.5 □ 8.75 □ 9 □ Other
11. New blade? ☐ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK)
C) INTRA-OPERATIVE RESULTS
1. Characteristics of suction and automated translation:
Was suction time longer or shorter than usual?
Was the suction good and stable during the pass:
 Was the forward movement smooth and regular?
2. Potential intra-operative events
Pseudo Button-hole ☐ Yes ☐ No
Unacceptable thickness
Button-hole □ Yes □ No
Partial flap □ Yes □ No
• Free cap ☐ Yes ☐ No
Decentred Flap □ Yes □ No
Stromal Incursion □ Yes □ No
Epithelium patch ☐ Yes ☐ No Totale
Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Flap complication report

EAQA018 / C

Approuvé(e) par:
Jean Paul MERCEREAU
Directeur Assurance Qualité et
Affaires réglementaires
le 06/07/2011 16:03:48

Date d'application : 06/07/2011

14560 Ahmad Hussein Patient file#: Surgeon: REPORT OF INTRAOPERATIVE FLAP COMPLICATION A) PATIENT OS 1. Eye K2 42,9 K1 Axis 7,3 K1 41.4 2. Keratrometries 3. Intra-op full corneal thickness (microns) 546 ☐ Ultrasound ☐ Imaging ☐ Scheimpflug camera 4. White-to-White (mm) 100 mm Pentacam ☐ Hyperopic 5 Ametropic correction? 6. Additional comments on the patient's eye _ B) MATERIAL □ Evo2 □ Evo3 □ Evo3E □Other Serial Number 1. Console 2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™ □ Evo2 Speed adaptator s/n _____ Speed selection □1 or □ 2 (For M2/M2SU and One Use Plus only) □ 150 □ 130 □ 110 □ 90 Serial Number: __ 3. Microkeratome metal head : +1487 SPK 4. Handpiece serial number : Single use LOT 144112 5. Blade Lot # or Single-Use Lot # 6.Moria sterile tubing Reference 19138 Batch number : <u>カリ ろに</u>の 7. On approximately how many eyes this specific set had been used before this complication? _ ☐Single use □H □-1 •20 □+1 +2 □ +3 □ -1 LC 8. Ring □Disposable □Other _ □8 □8.5 □8.75 □9 10 Stop ☐ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK) 11. New blade? C) INTRA-OPERATIVE RESULTS 1. Characteristics of suction and automated translation: If yes, suction time? _____ sec Was suction time longer or shorter than usual? .☐ Yes ☐ No Was the suction good and stable during the pass? Yes ☐ No Was the forward movement smooth and regular? 2. Potential intra-operative events If yes, what was the flap thickness in microns? Pseudo Button-hole ☐ Yes ☐ No Unacceptable thickness ☐ Yes ☐ No ❖Pre-op full corneal thickness Residual stromal bed thickness ☐ Yes ☐ No Button-hole ❖Calculated Flap thickness ☐ Yes ☐ No Partial flap ☐ Yes ☐ No Free cap ☐ Yes ☐ No Decentred Flap ☐ Yes ☐ No Stromal Incursion ☐ Yes ☐ No Epithelium patch

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Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

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Date d'application : 06/07/2011

Surgeon: Ahmad Hussein Patient file#: 14560 Date 17 June W

N 70	DEDO	RT OF INTRAC	DEDATIVE EI	AR COMPLIC	ATION	
A) PATIENT	KLIO	ICI OF INTINAC	T LIVATIVE I'L	Ar COMI LICA	ATION	
1. Eye	e ²	□ OD	14	⊿os		
2. Keratrome	tries	K1 41	O K2 4	2.6 K1 Axis	56.9	
3. Intra-op fu	II corneal thickness				ng □Scheimpflug	camera
	Vhite (mm) 12-1					,
5 Ametropic		Myop		eropic Astigi	matic	
(1) 5400 (0) 00 (0) 00 (0) 10 (0) (0)	comments on the	, , , ,	., –	epie — 2 ieugi		
B) MATERIAL	oon mo		*		<	
	□ Evo2 □ Evo3	☑ Evo3E □O	ther Serial Nu	mber :	8117	
2. Microkerat	ome ONE O	ONE Use C	в 🗆 свѕи 🗆 м	2 I M2SU	NE Use-Plus	EPI-k™
☐ Evo2 Si	oeed adaptator s	/n Spec	ed selection.	or □ 2 (For M2	M2SU and One U	se Plus only)
	ome metal head		110 🗆 90	Serial Number:		808 SUPPE BALL
4. Handpiece	serial number		187 SBK	1		
	# or Single-Use Lo		ale use	LOT 14411	2	
	e tubing Reference			12602		
	imately how many			Washington and the second of t	emplication?	
		☐Single use	OH 42-1	□0 □+1	□ +2 □ +3	– □ -1 LC
10 Stop		□ 7 □ 7.5		□ 8.75 □ 9	□Other	
11. New blad	e?	☐ Yes ☐ No (C			ilateral simultaneou	
	RATIVE RESULT					
OTHER DE LE	WIIVE NEODE	<u></u>				
Characteri	stics of suction and	l automated trans	slation:	2		
• Was	suction time longe	er or shorter than	usual?	If yes, s	suction time?	_ sec
	the suction good		ē	Yes	□ No	
• Was	the forward move	ment smooth and	l regular?	Yes	□ No	
2. Potential in	ntra-operative even	ts				
• Pse	udo Button-hole	☐ Yes ☐ No	If yes, what	was the flap thicl	kness in microns?	
 Una 	cceptable thicknes	s ☑ Yes ☐ No		❖Pre-op full co	rneal thickness	563
 Butter 	on-hole	☐ Yes ☐ No	n fi	❖Residual strop	mal bed thickness	480
 Part 	ial flap	☐ Yes ☐ No			ap thickness	83
 Free 	cap	☐ Yes ☐ No				
• Dec	entred Flap	☐ Yes ☐ No				
 Stro 	mal Incursion	☐ Yes ☐ No				
	nelium patch	☐ Yes ☐ No		ىم		
Draw the	location of the par	tial flap or of the	pseudo or "see-ti	hrough" button-h	ole	

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Moria

Date d'application : 06/07/2011

Surgeon: Dr. Ahmad Hussen Patient file#: 14578 Date 18 June 2015

6 7	REPO	RT OF INTRAOP	ERATIVE FI	LAP COMPLICA	ATION	
A) PATIENT						
1. Eye	973	200D		os os		
2. Keratro		к1 <u>40.</u>		1.0 K1 Axis)-1	
3. Intra-op	full corneal thicknes	s (microns) $\frac{\mathcal{I} \mathscr{L} \mathscr{L}}{\mathscr{L}}$	D Ultra	asound 🛭 Imagi	ng □Scheimpflug [°] c	amera
4. White-t	o-White (mm) <u> </u>	omn Perta	cam			
5 Ametro	oic correction?	⊈M yopiç	□ Нур	eropic	natic	
6. Additio	nal comments on the	patient's eye				- :
B) MATERIA 1. Consol	<u>L</u> e □ Evo2 □ Evo3	Evo3E □Oth	er Serial Nu	umber :	8113	
2. Microke	eratome ONE	ONE Use CB	□ CBSU □ M	M2 M2SU AC	NE Use-Plus □ Ef	PI-k™
□ Evo2	Speed adaptator s	/n Speed	selection 📭	or □ 2 (For M2	/M2SU and One Use	Plus only)
	eratome metal head		-			
	ece serial number	: 5148		γ.		
	ot # or Single-Use Lo			LOT 14411	2	
	erile tubing Reference					
	roximately how many				mplication?	
8. Ring	□Disposable			□ -0′ □ +1		⊒ -1 LC
10 Stop		7 7.5		Section 19 to the section 19 t	□Other	
11. New b	lade?				lateral simultaneous	I ASIK)
	PERATIVE RESUL		on no tor the	y codonia cyc in bi	ratorar omrananoodo	271077
C) INTRA-OI	LIVE KESSE	10				
1. Charac	teristics of suction an	d automated transla	ACCOUNT OF THE PROPERTY OF THE			
• V	Vas suction time long	er or shorter than u	sual? NO	If yes, s	uction time?	sec
• \	Vas the suction good	and stable during th	ne pass?	Yes	□ No	
• \	Vas the forward move	ement smooth and r	egular?	Yes	□ No	
2. Potentia	al intra-operative ever	nts				
	Pseudo Button-hole	☐ Yes ☐ No	If yes, what	was the flap thicl	kness in microns?	40
• (Jnacceptable thicknes	s , Yes 🗆 No	NO.	❖Pre-op full co	and the second of the second o	88,
	Button-hole	☐ Yes ☐ No	(3.5)		mal bed thickness <u>\</u>	OC TO
	Partial flap	☐ Yes ☐ No			ap thickness	<u> </u>
	ree cap	☐ Yes ☐ No				
	Decentred Flap	☐ Yes ☐ No				
	Stromal Incursion	☐ Yes ☐ No				·
• 1	pithelium patch	☐ Yes ☐ No		r		

EAQA018 / C

14578

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#

Date

Pre-op full corneal thickness

❖Calculated Flap thickness

Residual stromal bed thickness

7015

Moria

Date d'application : 06/07/2011

Ahmad

REPORT OF INTRAOPERATIVE FLAP COMPLICATION A) PATIENT øos OD D 1. Eye K2 41.2 K1 Axis 32.7 K1 41.0 2. Keratrometries 3. Intra-op full corneal thickness (microns) SO(o ☐Ultrasound ☐ Imaging ☐Scheimpflug camera 4. White-to-White (mm) 11.8 mm Pentacan 5 Ametropic correction? ☑ Myopic ☐ Hyperopic ☐ Astigmatic 6. Additional comments on the patient's eye _ B) MATERIAL 1. Console ☐ Evo2 ☐ Evo3 ☐ Evo3E ☐ Other Serial Number 2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™ □ Evo2 Speed adaptator s/n _____ Speed selection □1 or □ 2 (For M2/M2SU and One Use Plus only) □ 150 □ 130 □ 110 □ 90 3. Microkeratome metal head Serial Number: : T1487 SBK 4. Handpiece serial number : single use LOT 144112 5. Blade Lot # or Single-Use Lot # 6.Moria sterile tubing Reference 19138 Batch number : つりはったの2 7. On approximately how many eyes this specific set had been used before this complication? 8. Ring □Disposable ☐Single use OH O-1 ,21′0 □ +1 \Box +2 □ +3 □ -1 LC □8.5 □8.75 □9 10 Stop **17** □ 7.5 Other 11. New blade? ☐ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK) C) INTRA-OPERATIVE RESULTS 1. Characteristics of suction and automated translation: Was suction time longer or shorter than usual? NO If yes, suction time? _____ sec Was the suction good and stable during the pass? Yes No ☐ Yes Was the forward movement smooth and regular? ☐ No 2. Potential intra-operative events Pseudo Button-hole ☐ Yes ☐ No If yes, what was the flap thickness in microns?

Patient file#:

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

☐ Yes ☐ No

Unacceptable thickness Pres D No

Button-hole

Partial flap

Decentred Flap

Stromal Incursion

Epithelium patch

Free cap

EAQA018 / C

14601

Approuvé(e) par Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

Date d'application : 06/07/2011

Moria

Date

16 June 2015

Surgeon: Ahmad HU	ISSEM Patien	t file#:	1601	Date /	0 001.00 20
	RT OF INTRAOPER	RATIVE FLA	P COMPLICAT	<u> ION</u>	
A) PATIENT		U.			
1. Eye	□ OD		□os		
30	K1 42.2	K2 42	K1 Axis K	· <i>O</i>	
 Keratrometries Intra-op full corneal thickness 		Ultras	ound 🗆 Imagin	g Scheimr	oflug camera
3. Intra-op full corneal trickness	Lancier Restal				
4. White-to-White (mm) 12.	Min receive	☐ Hyper	opic	atic	
5 Ametropic correction?	Myopic	Tryper	opio a riougini		
6. Additional comments on the	patient's eye				
B) MATERIAL 1. Console □ Evo2 □ Evo3	Evo3E □Other	Serial Nur	ilbei	8113	TM
2. Microkeratome ☐ ONE ☐	ONE Use CB C	CBSU M2	M2SU -O	NE Use-Plus	☐ EPI-k
□ Evo2 Speed adaptator s	s/n Speed s	election 1	or □ 2 (For M2/	M2SU and Or	ne Use Plus only)
Microkeratome metal head	□ 150 □ 130 □	110 🗆 90	Serial Number:		
Handpiece serial number	. 1148	7 SBK			
5. Blade Lot # or Single-Use Lot	4 .	e use	LOT 144117	L	
6. Moria sterile tubing Reference	o 10138 Batch numb	er : 314	2602		
On approximately how many	e 19100 Baterific se	t had been us	ed before this co	mplication? _	
	/ eyes this specific sc] H ⊿2-1	□0 □+1	□ +2 □	+3 □-1 LC
8. Ring Disposable		8.5	□ 8.75 □ 9	□Other	
10 Stop	☐ 7 ☐ 7.5 ☐ Ves ☐ No (Chec	ا O.D اکس O.D ا			neous LASIK)
11. New blade?	Yes U No (Chec	CK "No" for the	Second eye in bi	latorar omrana	
C) INTRA-OPERATIVE RESUL	<u>.TS</u>				
Characteristics of suction a	nd automated translat	tion:			
und die allemater			If yes, s	suction time?_	sec
Was suction time ion Was the suction good	d and stable during th	e pass?	Yes	□ No	
• Was the forward mov	vement smooth and re	egular?	Yes	□ No	
vvas tile lottura mo		10 11 0			
Potential intra-operative ev		59		terra la mior	one?
 Pseudo Button-hole 	☐ Yes ☐ No	If yes, wha	t was the flap thic	kness in mich	SIST TYF
 Unacceptable thickn 	ess_ Yes No		❖Pre-op ruil co ❖Residual stro	mal hed thick	ness Lilele
 Button-hole 	☐ Yes ☐ No				8
 Partial flap 	☐ Yes ☐ No		* Calculated 1		
Free cap	☐ Yes ☐ No				
Decentred Flap	☐ Yes ☐ No ☐ Yes ☐ No				:
Stromal Incursion	☐ Yes ☐ No			~	(A)
 Epithelium patch 	1 162 C 140		995500 100	2 2	

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Moria

Date d'application : 06/07/2011

REPORT OF INTRAOPERATIVE FLAP COMPLICATION	Surgeon:	Ahmad	Hussan	Patient f	ile#:	14601	1	Date	16	June
A) PATIENT 1. Eye		R	EPORT OF IN	TRAOPERA	TIVE FL/	AP COM	PLICAT	<u>ION</u>		
2. Keratrometries	A) PATIENT	<u> </u>								
2. Keratrometries	1. Eye	2 8								
3. Intra-op full corneal thickness (microns)		netries	K1	42.4						į.
4. White-to-White (mm)			kness (microns)	JJY	Ultras	ound 🗆	Imaging	□Schei	impflug	camera
SAmetropic correction? Myopic Hyperopic Astigmatic	4. White-to	-White (mm)	12.3mm	pentaco	im					
B) MATERIAL 1. Console Evo2 Evo3 Evo3E Other Serial Number Ell Other Serial Number Ell Other Evo2 Decentred Flap Other Serial Number Ell Other Evo2 Other Other					☐ Hyper	ropic 🔎	Ástigma	tic		
1. Console Evo2 Evo3 Evo3 Evo3 Cother Serial Number Evo2 Microkeratome ONE ONE Use CB CBSU M2 M2SU Pront Dept-k Dept-k Cother Cother M2SU Pront Dept-k Dept-k Cother Coth	6. Addition	al comments or	n the patient's ey	e						 5
Evo2 Speed adaptator s/n	1. Console	e □ Evo2 □	Evo3 🗹 Evo3E	Other	Serial Nur	mber	:	113		
Evo2 Speed adaptator s/n	2. Microke	ratome ONI	E ☐ ONE Use	□ CB □ CE	3SU 🗆 M2	2 AM2SI	NO∕¤ L	E Use-Plu	ıs 🗆 E	EPI-k™
3. Microkeratome metal head 4. Handpiece serial number 5. Blade Lot # or Single-Use Lot # : SINGLE LOT LUGIT 6. Moria sterile tubing Reference 19138 Batch number : 1	□ Evo2	Speed adapta	ator s/n	_ Speed sele	ction 1	or 🗆 2 (I	For M2/N	12SU and	One Us	e Plus only
4. Handpiece serial number 5. Blade Lot # or Single-Use Lot # : Single Use Lot IUUID 6. Moria sterile tubing Reference 19138 Batch number : JU JUDD 7. On approximately how many eyes this specific set had been used before this complication? 8. Ring Disposable Single use H 21 0 0 + 1 + 2 + 3 - 1 LC 10 Stop 7 7.5 8 8 8.5 8.5 8.75 9 Other 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK) C) INTRA-OPERATIVE RESULTS 1. Characteristics of suction and automated translation: • Was suction time longer or shorter than usual? No Was the suction good and stable during the pass? • Was the forward movement smooth and regular? 1. Pseudo Button-hole Yes No Fre-op full corneal thickness in microns? • Unacceptable thickness Yes No Pre-op full corneal thickness Pre-op full corn			ead 🗆 150	□ 130 □ 11	0 🗆 90					
5. Blade Lot # or Single-Use Lot # : SINALY LICE LOT LUCID 6. Moria sterile tubing Reference 19138 Batch number 1 2000. 7. On approximately how many eyes this specific set had been used before this complication?				J1487	_JBK		f.			
6.Moria sterile tubing Reference 19138 Batch number			se Lot# :	Single U	use Lot	1441	12			
7. On approximately how many eyes this specific set had been used before this complication? 8. Ring	6 Moria st	erile tubina Refe	erence 19138 B	atch number	3143	602				
8. Ring Disposable Single use	7 On ann	rovimately how	many eves this	specific set ha	ad been us	ed before	this com	plication?		<u></u>
10 Stop										□ -1 LC
11. New blade?	2000	GD topocasie				□ 8.75	□ 9	□Other		<u>.</u>
1. Characteristics of suction and automated translation: Was suction time longer or shorter than usual? Was the suction good and stable during the pass? Was the forward movement smooth and regular? Pseudo Button-hole	7000 PMD - 0	lada?						teral simu	iltaneou	is LASIK)
1. Characteristics of suction and automated translation: • Was suction time longer or shorter than usual? No			2							
Was suction time longer or shorter than usual? Was the suction good and stable during the pass? Was the forward movement smooth and regular? Pseudo Button-hole										
Was the suction good and stable during the pass? Was the forward movement smooth and regular? Per on the latter of the latter	1. Charac	teristics of sucti	on and automate	ed translation	٠ س١					
Was the suction good and stable during the pass? Was the forward movement smooth and regular? Per on the latter of the latter	• \	Nas suction time	e longer or short	er than usual	? NU				?	_ sec
2. Potential intra-operative events Pseudo Button-hole Yes No Spre-op full corneal thickness in microns? Partial flap Yes No Stromal Incursion Yes No No Stromal Incursion Yes No No Yes No Y	• \	Was the suction	good and stable	during the pa	ass?		_	7.00		
Pseudo Button-hole	• 1	Was the forward	I movement smo	oth and regul	ar?	/	∠ Yes	U NO		
Unacceptable thickness Yes	2. Potenti	ial intra-operativ	e events							
Button-hole	•	Pseudo Button-	hole	□ No If	f yes, what					75.0
Partial flap	•	Unacceptable th	nickness 2Yes	□ No						117
Free cap	•	Button-hole								30
Decentred Flap	•	Partial flap					lated Fla	p thicknes	S	
Stromal Incursion ☐ Yes ☐ No Epithelium patch ☐ Yes ☐ No		- ES								
Epithelium patch □ Yes □ No T		BE-ERRORENWIN-SERVICE THE SER								
• Epithelium patch — Tes Like Prove the location of the partial flan or of the pseudo or "see-through" button-hole							لم			*
	Deau	Epithelium patc	n ures	or of the pseud	do or "see-	-through" b	outton-ho	ole		

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Date d'application : 06/07/2011

Surgeon: Ahmad Hussein

Patient file#:

14610 1

Date

A JUNE 2015

the section of the se
REPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT
1. Eye OD OS
2. Keratrometries K1 4.2 K2 4 K1 Axis 17-7
3. Intra-op full corneal thickness (microns) <u> </u>
4. White-to-White (mm) 12.4 mm Rentacam
5 Ametropic correction?
6. Additional comments on the patient's eye
B) MATERIAL 1. Console □ Evo2 □ Evo3 □ Evo3E □Other Serial Number : □ 【[]
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™
☐ Evo2 Speed adaptator s/n Speed selection ☐ or ☐ 2 (For M2/M2SU and One Use Plus only
3. Microkeratome metal head ☐ 150 ☐ 130 ☐ 110 ☐ 90 Serial Number:
4. Handpiece serial number : JI487 (RK
5. Blade Lot # or Single-Use Lot # : Single use Lot 144112
6.Moria sterile tubing Reference 19138 Batch number : 214 31007
7. On approximately how many eyes this specific set had been used before this complication?
8. Ring
10 Stop
11. New blade? ☐ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK)
C) INTRA-OPERATIVE RESULTS
C) INTRA-OFERATIVE RESULTS
Characteristics of suction and automated translation:
 Was suction time longer or shorter than usual? NO If yes, suction time? sec
 Was the suction good and stable during the pass? □ Yes □ No
Was the forward movement smooth and regular? □Yes □ No
2. Potential intra-operative events
 Pseudo Button-hole ☐ Yes ☐ No If yes, what was the flap thickness in microns?
Unacceptable thickness ☑ Yes ☐ No
Button-hole ☐ Yes ☐ No
Partial flap □ Yes □ No
Free cap □ Yes □ No
Decentred Flap □ Yes □ No
Stromal Incursion □ Yes □ No
Epithelium patch □ Yes □ No P
Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Flap complication report EAQA018 / C Approuvé(e) par Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 Date d'application : 06/07/2011

Surgeon: Ahmad Hussein Patient file#: 14610 Date 17 June
REPORT OF INTRAOPERATIVE FLAP COMPLICATION
A) PATIENT
1. Eye □ OD ØOS
2. Keratrometries K1 40.9 K2 41.7 K1 Axis 7.4
3. Intra-op full corneal thickness (microns) <u>⟨⟨⟨⟨⟩</u> □ □ Ultrasound □ Imaging □ Scheimpflug camera
4. White-to-White (mm) 12.4 mm pentacam
5 Ametropic correction? ☐ Myopic ☐ Hyperopic ☐ Astigmatic
6. Additional comments on the patient's eye
R) MATERIAL
1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☑ ONE Use-Plus ☐ EPI-k™
☐ Evo2 Speed adaptator s/n Speed selection ☐ or ☐ 2 (For M2/M2SU and One Use Plus only
3. Microkeratome metal head
4. Handpiece serial number : <u>J1487</u> SBK
5. Blade Lot # or Single-Use Lot # : Single Use Lot 1144112
6.Moria sterile tubing Reference 19138 Batch number : 7147 (007.
7. On approximately how many eyes this specific set had been used before this complication?
8. Ring Disposable Disingle use
10 Stop
11. New blade?
C) INTRA-OPERATIVE RESULTS
<u> </u>
1. Characteristics of suction and automated translation:
Was suction time longer or shorter than usual? If yes, suction time? sec
Was the suction good and stable during the pass? □ No
Was the forward movement smooth and regular? □ No
2. Potential intra-operative events
Pseudo Button-hole ☐ Yes ☐ No ☐ If yes, what was the flap thickness in microns?
 Unacceptable thickness ✓ Yes ☐ No Pre-op full corneal thickness
Button-hole ☐ Yes ☐ No
 Partial flap ☐ Yes ☐ No Calculated Flap thickness
Free cap □ Yes □ No
Decentred Flap □ Yes □ No
Stromal Incursion □ Yes □ No
Epithelium patch □ Yes □ No
Draw the location of the partial flap or of the pseudo or "see-through" button-hole

EAQA018/C

Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

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Moria

Date d'application : 06/07/2011

Surgeon: Ahmad Hussem Patient file#: 14519 Date 14 June 200

(9)	DEDORT OF WITH COLOR OF THE COL	
A) PATIENT	REPORT OF INTRAOPERATIVE FLAP COMPLICATION	
1. Eye	□ os	
2. Keratrometries	K1 39.6 K2 41.2 K1 Axis 179.6	
3. Intra-op full cornea	al thickness (microns)	, camera
	im) 12.7 mm calliper	, camora
5 Ametropic correctio	See	
N#2	nts on the patient's eye	
B) MATERIAL	9	
1. Console ☐ Evo2	2 D Evo3 D Evo3E DOther Serial Number :	
2. Microkeratome	ONE ONE Use OCBOCBSU M2 M2SU TONE Use-Plus	EPI-k™
☐ Evo2 Speed ad	daptator s/n Speed selection □1 or □ 2 (For M2/M2SU and One Us	se Plus only)
	etal head	
4. Handpiece serial no	÷	
5. Blade Lot # or Sing		
	Reference 19138 Batch number : 7143 402	
	how many eyes this specific set had been used before this complication?	
8. Ring □Disposa		- □ -1 LC
10 Stop	□7 □7.5 □8 □8.5 □8.75 □9 □Other	_ , _ ,
11. New blade?	Yes No (Check "No" for the second eye in bilateral simultaneou	s I ASIK)
C) INTRA-OPERATIVE		o Eriony
Characteristics of second control of the second control of th	suction and automated translation:	
	time longer or shorter than usual? If yes, suction time?	_ sec
	tion good and stable during the pass?	
Was the forw	vard movement smooth and regular?	
2. Potential intra-opera	rative events	
 Pseudo Butto 	on-hole Yes No If yes, what was the flap thickness in microns?	
 Unacceptable 	le thickness ☐ Yes ☐ No ❖Pre-op full corneal thickness	564
 Button-hole 	☐ Yes ☐ No	496
 Partial flap 	☐ Yes ☐ No	68
 Free cap 	☐ Yes ☐ No	
 Decentred Flag 	lap ☐ Yes ☐ No	
 Stromal Incur 		•
 Epithelium pa 	CHESTONIAN STONE SHANNING MICHOLOGISMA	
Draw the location	of the partial flap or of the pseudo or "see-through" button-hole	

EAQA018 / C

Approuvé(e) par Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48

Moria

Date d'application: 06/07/2011

14519 June vols Ahmad Hussein Surgeon: Patient file#: Date REPORT OF INTRAOPERATIVE FLAP COMPLICATION A) PATIENT 1. Eye OD K2 41.0 K1 Axis 170.9 K1 39.5 2. Keratrometries 3. Intra-op full corneal thickness (microns) $\frac{\int \mathcal{Q}}{\int}$ ☑ Ultrasound ☐ Imaging ☐ Scheimpflug camera Calliper 4. White-to-White (mm) 12:3 mm 5 Ametropic correction? Myopic ☐ Hyperopic ☐ Astigmatic 6. Additional comments on the patient's eye _ B) MATERIAL 1. Console ☐ Evo2 ☐ Evo3 ☐ Evo3E ☐ Other Serial Number 2. Microkeratome ☐ ONE ☐ ONE Use ☐ CB ☐ CBSU ☐ M2 ☐ M2SU ☐ ONE Use-Plus ☐ EPI-k™ □ Evo2 Speed adaptator s/n _____ Speed selection ☐ or □ 2 (For M2/M2SU and One Use Plus only) □ 150 □ 130 □ 110 □ 90 3. Microkeratome metal head Serial Number: ____ : J1487 SBK 4. Handpiece serial number WT 144112 : Single use 5. Blade Lot # or Single-Use Lot # 6.Moria sterile tubing Reference 19138 Batch number : カリ カルの 7. On approximately how many eyes this specific set had been used before this complication? ___ OH 40-1 8. Ring □ Disposable ☐Single use +1 +2 □ +3 □ -1 LC 12 8 □ 8.5 □ 8.75 □ 9 □ 7.5 □Other 10 Stop 11. New blade? ☐ Yes ☐ No (Check "No" for the second eye in bilateral simultaneous LASIK) C) INTRA-OPERATIVE RESULTS 1. Characteristics of suction and automated translation: If yes, suction time? _____ sec Was suction time longer or shorter than usual? Was the suction good and stable during the pass? Yes No Yes No Was the forward movement smooth and regular? 2. Potential intra-operative events Pseudo Button-hole ☐ Yes ☐ No If yes, what was the flap thickness in microns? Unacceptable thickness - Yes No Pre-op full corneal thickness Button-hole ☐ Yes ☐ No ❖Residual stromal bed thickness <u>< 6 €</u> Partial flap ☐ Yes ☐ No ❖Calculated Flap thickness Free cap ☐ Yes ☐ No Decentred Flap ☐ Yes ☐ No Stromal Incursion ☐ Yes ☐ No

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☐ Yes ☐ No Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Epithelium patch